GUIDELINES FOR THE DEVELOPMENT OF ALTERED STANDARDS OF CARE FOR INFLUENZA PANDEMIC

I. Public Health Goals

A. Control pandemic to extent possible; protect public from mass outbreak of disease and resultant morbidity and mortality.

B. Maximize positive patient outcomes when health care needs exceed available resources.

C. Establish principles and guidelines to assist health care providers to continue to provide care in an ethical manner during circumstances which make delivery of health care services in the normal course difficult, if not impossible.

D. Establish process **directed by DPH** for determining priorities for the use of limited health care resources and altered standard of care clinical protocols (ASC protocols) for health care providers, including health care practitioners at all levels and all institutions and entities which deliver health care.

- To the extent possible, have in place, prior to an influenza pandemic, these priorities and ASC protocols.

- Establish process for reevaluating these priorities and ASC protocols during an influenza pandemic to reflect changing conditions and circumstances. It is anticipated that the principles in these guidelines will remain constant and that any changes in priorities or clinical protocols will be made in conformance with these principles.

II. Process for Decision Making on:

(1) Priorities for the Allocation of Limited Health Care Resources; and
(2) ASC Protocols

These Draft Principles for priorities and ASC protocols have been developed by the Department of Public Health (DPH) in consultation with an advisory group, convened jointly by the Harvard School of Public Health and DPH, which included ethicists,

lawyers, clinicians, and local and state public health professionals. (See Section III below.)

A. **(DELETE: Health care allocation priorities and ASC protocols may be implemented, as necessary, at the direction of DPH following a Declaration of a Public Health Emergency or State of Emergency by the Governor.) Following a declaration by the Governor that there is an emergency which is detrimental to the public health, the Commissioner of Public Health may, if he deems such action necessary to assure the maintenance of public health during such period of emergency, order adherence to the ASC priorities and protocols.**

B. Priorities for distribution of limited medications and other supplies not addressed by ASC protocols will be determined by DPH with input from an Advisory Committee of health care provider representatives and consumers (DPH ASC Advisory Committee). See Section III below for principles to guide prioritization of certain groups.

C. ASC protocols will be prepared by the provider members of the DPH ASC Advisory Committee in consultation with DPH.

D. Priorities and ASC protocols will be:

- Set in advance of an influenza pandemic to the extent possible
- Based on principles of distribution of limited resources outlined in Section III below
- Proportional to the existing conditions; implemented only as necessary
- Consistent across the Commonwealth with appropriate local control/implementation/health care provider discretion
- Implemented at provider/institution level in conformance with guidelines
- Subject to continuous review and reassessment by DPH and the DPH ASC Advisory Committee

III. DRAFT Principles for Allocation of Limited Resources and ASC Protocols

The following draft principles are based on the recommendations of the joint advisory group convened by DPH and the Harvard School of Public Health.

A. Priority for limited medical resources and ASC protocols will be based upon the allocation of scarce resources to maximize the number of lives saved **DELETE:("the greatest good for the greatest number")**. This allocation will be:

(1) Determined on the basis of the best available medical information, clinical knowledge, and clinical judgment;

(2) Implemented in a manner that provides equitable treatment of any individual or group of individuals based on the best available medical information, clinical knowledge, and clinical judgment;

Among practices *inconsistent* with equitable treatment would be:

Giving to individuals or groups privileged access to resources on the grounds that they are family, friends, or acquaintances.

Failure to make reasonable efforts to insure that economically underprivileged groups receive needed resources.

(3) Implemented without discrimination or regard to sex, sexual orientation, race, religion, ethnicity, **disability, age**, income **or insurance status.**

Age and/or disability may be considered along with other risk factors in allocating resources to save as many lives as possible, but the importance of saving the elderly or people with disabilities is the same as for others. The assessment of risk factors should be made on the basis of the best available medical information, clinical knowledge, and clinical judgment.

B. **(DELETE**: **"Priority directives and ASC protocols will include flexibility and physician discretion to vary priorities and make exceptions based on:**")** **Priority directives and ASC protocols will permit flexibility for physician discretion to vary priorities and protocols and/or make exceptions to them based on:**

- Good faith judgment; and
- Circumstances which warrant exception from the ASC protocols

Such exceptions will be subject to a prior expedited review process established by the health care institution.

Health care institutions will establish capacity for expeditious review of exceptions. (Depending on ability to act immediately, possibly the Institutional Review Board, other group formed for this purpose, or designated ethics consultant or peer consultant, with alternates assigned for continuity of operations).

C. Health care institutions and providers have a responsibility to develop mutual aid plans on a regional basis to ensure communication and mutual assistance during the pandemic.

D. ASC protocols will recognize:

- Any changes in practices necessary to provide care under conditions of scarce resources or overwhelming demand for care
- An expanded scope of practice for health care providers
- The use of alternate care sites, such as influenza special care units at facilities other than health care facilities
- Reasonable, practical standards for documentation of delivery of care

E. The responsibility of health care providers is to protect the public's health by adhering to principles/ASC protocols/priorities developed for a pandemic situation.

F. Patient care must be provided within the context and limitations of the altered standards of care necessitated by the public health emergency.

- It is acknowledged that there is an inherent tension between the health care providers' usual duty to their individual patients and their duty to maximize the number of lives saved during a pandemic. Health care providers and their affiliated health care institutions and entities should establish capacity for expeditious assistance for providers in making these decisions, using one of the peer mechanisms described in section III.B. above.

G. The Commonwealth and/or individual employers have a duty to prioritize the care and protection of health care providers whose work puts them at risk of significant morbidity or mortality.

IV. Communication

A. The goal should be transparency of decision-making: communication to the health care provider community and the public about the decision-making process, priorities and protocols and the basis for these priorities and protocols. Communication should be made by effective methods and formats.

B. Public outreach via public service announcements and other forms of communication should stress DPH's existing and ongoing collaboration with the universe of health care providers, hospitals, and others in developing protocols and procedures.

C. Public health officials should disclose as much information as necessary to protect public health without releasing personal identifying information in a manner which is consistent with state and federal law.

V. Individual Rights

Civil liberties and patients' rights will be protected to the greatest extent possible; however, it is recognized that the protection of the public health may require limitations on these liberties and rights during an influenza pandemic.

VI. Provider Liability

Health care providers who provide care in accordance with the priorities and ASC protocols developed by DPH and the DPH ASC Advisory Committee, including care provided outside of their scope of practice or scope of license, will be considered to have provided care at the level at which the average, prudent provider in a given community would practice.

Any individual patient to whom an approved, altered standard of care is provided should have no basis to assert in a medical malpractice claim against the health care provider that an appropriate level of care was not provided. Moreover, the health care provider, having met the requisite standard of care, should not be held liable in a malpractice action based on the provision of care in accordance with an approved, altered standard of care.